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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 11/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/788,286

Applicant(s)

GOSHE ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 15-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-14 and 24-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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(1) The Eidenmuller et al reference cited on form PTO-1449 has not been received nor considered.

(2) Claims 15-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

(3) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

(4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(5) Claims 1-14 and 24-27 are rejected under 35 USC 112, second paragraph, as being confusing and indefinite for the following reasons.

**a)** Claim 1, drawn to "a method of comparing the phosphorylation states of one or ore proteins in two or more samples", recites no method steps which would constitute any "comparing". The combination of the "providing", "reacting", "capturing", "releasing", and "detecting" steps of claim 1 do not provide any comparison.

**b)** It is unclear from the language of claim 1 whether the "one or more proteins" being compared for phosphorylation states are the **same** or **different** protein(s) for each of the multiple samples. See also, claim 9.

**3)** It is unclear from the language of claim 1 whether the "two or more samples" are being treated together in the recited method or whether each sample is being treated separately.

**4)** In claim 1, line 11 of page 31, there is no antecedent basis for the term "amino acid residues". It is suggested that this term be modified to --amino acid residues of the proteins--.

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**5)** In claim 1, it is unclear what is meant by "**the** capture reagent". Are the "capture reagent" and "binding agent" pair the same moieties used for all of the samples?

**6)** In claim 1, it is unclear what the purpose is of first "capturing bound proteins...using the capture reagent" and then "releasing captured bound proteins from the capture reagent by disrupting the interaction between the binding agent and the capture reagent". These two steps merely form a capture reagent-B bond and then break the same bond again.

**7)** In claim 1, it is unclear what is meant by the term "formerly phosphorylated". Does this mean that the amino acid residues of the protein samples do not contain phosphate groups?

**8)** The term "amount" of claim 4 is inconsistent with the "method of comparing" of independent claim 1 where no concentrations are being determined. See also, claim 9.

**9)** The requirement of claim 1 for "two or more samples" is inconsistent with "a single sample" and "a sample" of dependent claims 7 and 8 respectively.

**10)** In claim 9, the term "measuring relative abundances...labeled proteins" does not make sense.

**11)** In claim 12, the last line, the term "or at different times" does not make sense.

**12)** In claim 24, the last line, it is unclear exactly what is detected in the step of "detecting the tagged protein" and it unclear how this step is correlated with "a method of detecting more than one type of phosphorylated amino acid residue in a protein" recited in the first and second lines of the claim.

**13)** In claim 24, lines 6 and 14-15 of page 35, there is no antecedent basis for the term "each sample". It is also unclear as to how many samples the method is being applied to. The claim preamble recites "**a** protein" indicating that there is only one sample.

**14)** In claim 24, the term "differentially isotopically labeled protein reactive reagents" is used multiple times. However, it is unclear how the different moieties are "differentially" labeled relative to each other. For example, must the tyrosine residue be labeled differently from the serine or threonine residue(s) {not required by the claim language}? Is the "B-L-PhRG" reagent used the same for all of the amino acids?

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**(6)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**(7)** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**(8)** Claims 1-14 are rejected under 35 U.S.C. 102(a)<sup>(e)</sup> as being anticipated by Aebersold et al (WO 00/11208) or Aebersold et al (US 2002/0049307).

Aebersold et al (WO) describe the method of instant claim 1 wherein one or more protein functions in one or more samples is identified using a differentially isotopically labeled reagent which is the same as the reagent B-L-PhRG of instant claim 1. See the reagent A-L-PRG of claim 1 of the WO patent. The moiety "B" defined as "a binding agent that selectively binds to a capture reagent (CR)" of instant claim 1 is the same as the moiety "A" of the WO patent defined as "an affinity label that selectively binds to a capture reagent". The protein reactive group PRG of the WO patent can be a phosphate reactive group (see page 15, line 3 of the patent) which is the same as the phosphate reactive group PhRG of instant claim 1. The features of the dependent claims e.g. mass spectrometry detection, analysis of proteins from organelles or subcellular fractions, etc. are described by Aebersold et al (see claims 5 and 17 of the WO patent). See also Aebersold et al (US): page 3, paragraphs [0020] and [2005]; page 4, paragraphs [0032] and [0035]; page 7, paragraph [0065].

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**(9)** Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **(a)** Aebersold et al (WO 00/11208) or Aebersold et al (US 2002/0049307) taken in combination with **(b)** Haystead et al (US 5,686,310).

The Aebersold et al references are applied for the reason stated above in the rejection of claims 1-14 over 35 USC 102(a).

Haystead et al describe a method for simultaneously and differentially measuring phosphorylated serine, threonine and tyrosine in a protein sample using a fluorescence-based assay (see claims 1, 6, and 12). Haystead et al does not use a differentially labeled isotope method of detection as in the claimed invention.

In view of the fact that phosphotyrosine, phosphoserine, and phosphothreonine are well known amino acid derivatives which are routinely differentially assayed together (Haystead et al, in particular, claim 6), it would be obvious, as claimed, to assay these specific phosphorylated amino acids using the differentially isotopically labeled reagents of Aebersold et al which are known to be useful to detect phosphopeptides in general.

**(10)** Goodlett (US 2002/0115056: paragraphs [0115] and [0017]) is cited to further show the state of the art.


**(11)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

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Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

November 21, 2002

  
Mary E. (Molly) Ceperley  
Primary Examiner  
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